UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,556	11/16/2001	Jordan U. Gutterman	CLFR:009US	5224

52034 7590 11/12/2008

FULBRIGHT & JAWORSKI, L.L.P.
600 CONGRESS AVENUE
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
WEBB, WALTER E	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
11/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/992,556	GUTTERMAN ET AL.	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,9,10,22-32,39,41 and 44-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,9,10,22-32,39,41 and 44-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/4/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 8/21/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112--NEW

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 9, 10, 22-32, 39, 41 and 44-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant states that the structure of claim 1 is as recited in claim 21, and that the replacement of the methyl group for the hydrogen was a typographical error. They argue that support for the correction can be found in figures 39, 40, and 41. However, these figures do not show support for a typographical error. The figures show examples of triterpene glycosides. Claim 21 is completely supported by the specification at page

8. There is no discrepancy between claim 21 and the specification that would lead one to believe there was a typographical error. Since there is no support for a typographical error, the addition of the methyl group in conjunction with the limitations of "a)" and "b)" constitutes new matter.

Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 9, 10, 22-32, 39, 41 and 44-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "further defined" which renders the claim indefinite insofar as it is appended to definite terms "rheumatoid arthritis" and "inflammatory bowel disease." Appending these diseases as "further defined" renders their modifying function unclear.

Claim Rejections - 35 USC § 103--NEW

1) Claim 1, 2, 9, 10, 24-28, 31-32, 41 and 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable Arntzen et al., (US 6,444,233) and further in view of Ni et al., (US 5,965,421).

Arntzen et al., taught previously, differs from the instant claim insofar as it does not teach rheumatoid arthritis or inflammatory bowel disease.

Ni et al. teach that disregulation of NF-kB activation has been linked to rheumatoid arthritis and inflammatory bowel disease. (See col. 16, lines 5-12.)

Ni et al. does not teach the monoterpene of claim 1.

It would have been obvious to a person having ordinary skill in the art to have used the compounds of Arntzen to treat rheumatoid arthritis or inflammatory bowel disease, since these diseases are inflammatory diseases and the compounds of Arntzen are useful in treating inflammation. The artisan would have motivated to use the compounds of Arntzen to treat these diseases since the compounds of Arntzen inhibit NF-kB, and rheumatoid arthritis and inflammatory bowel disease are known to be treated by inhibiting NF-kB, as evidenced by Ni et al.

2) Claim 1, 2, 9, 10, 24-28, 31-32, 41, and 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arntzen et al., (WO 1999/59578) and further in view of Ni et al., (US 5,965,421).

Arntzen et al., taught previously, differs from the instant claim insofar as it does not teach rheumatoid arthritis or inflammatory bowel disease.

Ni et al. teach that disregulation of NF-kB activation has been linked to rheumatoid arthritis and inflammatory bowel disease. (See col. 16, lines 5-12.)

Ni et al. does not teach the monoterpene of claim 1.

It would have been obvious to a person having ordinary skill in the art to have used the compounds of Arntzen to treat rheumatoid arthritis or inflammatory bowel disease, since these diseases are inflammatory diseases and the compounds of

Arntzen are useful in treating inflammation. The artisan would have motivated to use the compounds of Arntzen to treat these diseases since the compounds of Arntzen inhibit NF-kB, and rheumatoid arthritis and inflammatory bowel disease are known to be treated by inhibiting NF-kB, as evidenced by Ni et al.

3) Claims 22-23 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arntzen et al., (US 6,444,233) as applied to claims 1, 2, 9, 10, 24-28, 31-32, 41 and 44-52 above, and further in view of Ni et al., (US 5,965,421).

Arntzen et al. differs from the instant claims insofar as it does not teach cis-, trans-, optical-, or stereo- isomers of the monoterpene as part of the composition.

Compounds, which are position isomers (compounds having the same radicals in physically different positions on the same nucleus), are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. (See MPEP 2144.09.) Therefore, isomers of the composition of Arntzen et al. are *prima facie* obvious.

4) Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arntzen et al., (US 6,444,233) as applied to claims 1, 2, 9, 10, 24-28, 31-32, 41 and 44-52 above, and further in view of Ni et al., (US 5,965,421).

Arntzen differs from the instant claim 39 insofar as it does not teach where the concentration administered is from about 0.5 to about 2.0 μg/ml.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP 2144.05 IIA.

It would have been obvious to a person having ordinary skill in the art to have administered the compounds of Arntzen et al. a concentration from about 0.5 to about 2.0 µg/ml to a subject. For example, Arntzen teaches administering an amount of 1mg/kg/day, which is also 1µg/g/day. (See col. 53, lines 35-51) Administration to a mouse weighing 20 g would mean administering 20 µg/day. That amount in 10ml of water would give a concentration of 2.0 µg/ml. This type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Nonstatutory Obvious-type Double Patenting--previous

Claims 1, 2, 9, 10, 22-32, 39, 41, 46 and 48-51 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 16-21 of U.S. Patent No. 6,962,720.

Applicant argues that the above claims are not obvious over the claims of the '720 patent since the '720 patent does not mention rheumatoid arthritis or inflammatory bowel disease. However, it would have been obvious to a person having ordinary skill in the art to treat rheumatoid arthritis or inflammatory bowel disease since these are diseases of inflammation. The artisan would have envisaged that the method of treating

inflammation of the '720 patent, included diseases such as rheumatoid arthritis or inflammatory bowel disease since they are well known inflammatory diseases.[1]

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

[1] See Ni. et al., (US 5,965,421) at col. 16, lines 5-12.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612